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EXAMINER	
MOULTON, ELIZABETH ROSE	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,214	MOGENSEN ET AL.	
	Examiner	Art Unit	
	ELIZABETH R. MOULTON	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/22/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *60-64* is/are allowed.

6)☒ Claim(s) *50-59, 65-72, 78-100* is/are rejected.

7)☒ Claim(s) *73-77* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

1. Claims 60-64 are allowed.

1. Claims 73-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 50, 56, 67, 69-72, 78, 80-88, 90-96 and are rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (US 5,527,287).

Miskinyar teaches a sterile insertion set with housing (74) and cannula (22); a plunger (18); a lock (56); a spring (70); a forward end (62), a cover (72) covering an opening (60). As to claim 82-85, engagement areas on button (33); claim 86-88, back cover (38).

4. Claims 93-96 are rejected under 35 U.S.C. 102(e) as being anticipated by Safabash et al (US 6,293,925).

Safabash teaches an injector device with an infusion set having a housing (400) and a cannula (402) with tubing (412); a device housing (500), a cover (414), a plunger (504), a spring drive (507), lock (552), and manually deformable housing/trigger (508) to release the plunger. See Figs 35-40g. See adhesive (406).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar as applied to claims above, and further in view of Teeple, Jr (US 5,807,316). Miskinyar does not teach indicia relating to the shelf life of the device on the cover. Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device (Col 18 line 25).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the indicia of Teeple to avoid providing an expired device to the patient.

3. Claims 50-59, 65-72, and 78-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash as applied above, and further in view of Miskinyar. Safabash teaches an injector device with an infusion set having a housing (400) and a cannula (402) with tubing (412); a device housing (500), a cover (414), a plunger (504), a spring drive (507), lock (552), and manually deformable housing/trigger (508) to

release the plunger. See Figs 35-40g. See adhesive (406). See glucose sensor Col 1 line 31. Safabash does not teach that the injector device is sterilized.

Miskinyar teaches a subcutaneous injector which is sterile and provided with front (72) and back (38) covers. Safabash teaches a front cover (414,416) only. It is well known in the medical arts to provide sterile devices, especially when the devices pierce the skin, in order to prevent infection and the spread of disease. Miskinyar teaches a similarly shaped (flatten round disc) device which similar plunger (spring powered, button actuated) which may be sterilized and has front and back covers. The front cover of Miskinyar is a thin membrane, similar to the adhesive cover of Safabash. The rear cover prevents unwanted discharge of the plunger.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the front and back covers of Miskinyar with the device of Safabash to provide a sterile insertion set, in order to prevent infection and the spread of disease.

As to claims 69-71, 86-88, 90-92 and 100 :Safabash does not teach a second cover on the back of the device. Miskinyar teaches a needle holder with rigid upstanding cover (38) and membrane cover (72). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the duplicate covers of Miskinyar in order to prevent accidental firing of the device and allow the device to be sterilized for the patient's use.

Response to Arguments

Miskinyar:

Infusion set: the phrase “infusion set” is not given a special definition in the specification. One ordinary skill in the art would consider a needle an infusion set. Furthermore, there is nothing in the claims that the infusion set is removable, either before or after placement of the needle in the patient. The term "removable" is a capability term and the needle is capable of being removed by cutting ,etc. In a device claim, the device must only be CAPABLE not INTENDED or DISCLOSED as performing the claimed function. There is no “plain meaning" of the term “infusion set” which limits an infusion set to a device removable from an "injector device" (which is also NOT given a special definition). An infusion set may be a pump, an IV bag, essentially anything with a fluid conduit for subcutaneous fluid delivery.

Cover: Miskinyar teaches two covers: 72 and 38. Cover 72 closes off a part of the infusion set as shown in Fig 2. The cover also “receives” a part of the infusion device when the needle pierces the tape, Fig 3. The hole through which the needle extends is obviously hollow. The examiner notes that the "front end portion" of the housing can be EITHER end of the housing.

Manually deformable housing: the button 33 is a part of the housing, generally housing 10. Applicant has absolutely no basis for asserting that the button, which actually forms a top of the housing, should no be considered a housing. Applicant asserts this does not fit the plain meaning of housing, but does NOT describe what such a plain meaning would be. The button moves up

and down, which makes it manually deformable from a first (up) to a second (down) position. The button may be pushed at the sides to deploy the plunger.

Safabash:

Housing: the button 508 is a part of the housing, generally housing 502. Applicant has absolutely no basis for asserting that the button, which actually forms a top of the housing, should no be considered a housing. Applicant asserts this does not fit the plain meaning of housing, but does NOT describe what such a plain meaning would be. The button moves up and down, which makes it manually deformable from a first (up) to a second (down) position. The button may be pushed at the sides to deploy the plunger. The prior art does not need to refer to its device using the same terminology as the applicant. References to Funderbunk are completely irrelevant as Safabash discloses an entirely different embodiment of the infusion placement device.

Cover: The term "removably connected" does not require a direct bond between the device housing and the cover. The cover is connected to the housing via the insertion set, as is clearly shown in Fig 40b. Safabash teaches a needle cover (414) and adhesive backing (416) COVERING adhesive 406

Miskinyar and Teeple:

Miskinyar and Teeple are both related to subcutaneous injections which places them in related fields of endeavor. The desire to improve the safety of medical devices is a well recognized motivation for improvement. In this case, Teeple teaches labeling a medical device with expiration data. It would be a clear

case of improving similar devices in the same way to add expiration data to the device of Miskinyar.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MOULTON whose telephone number is (571)272-9970. The examiner can normally be reached on 7:00-3:30 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767